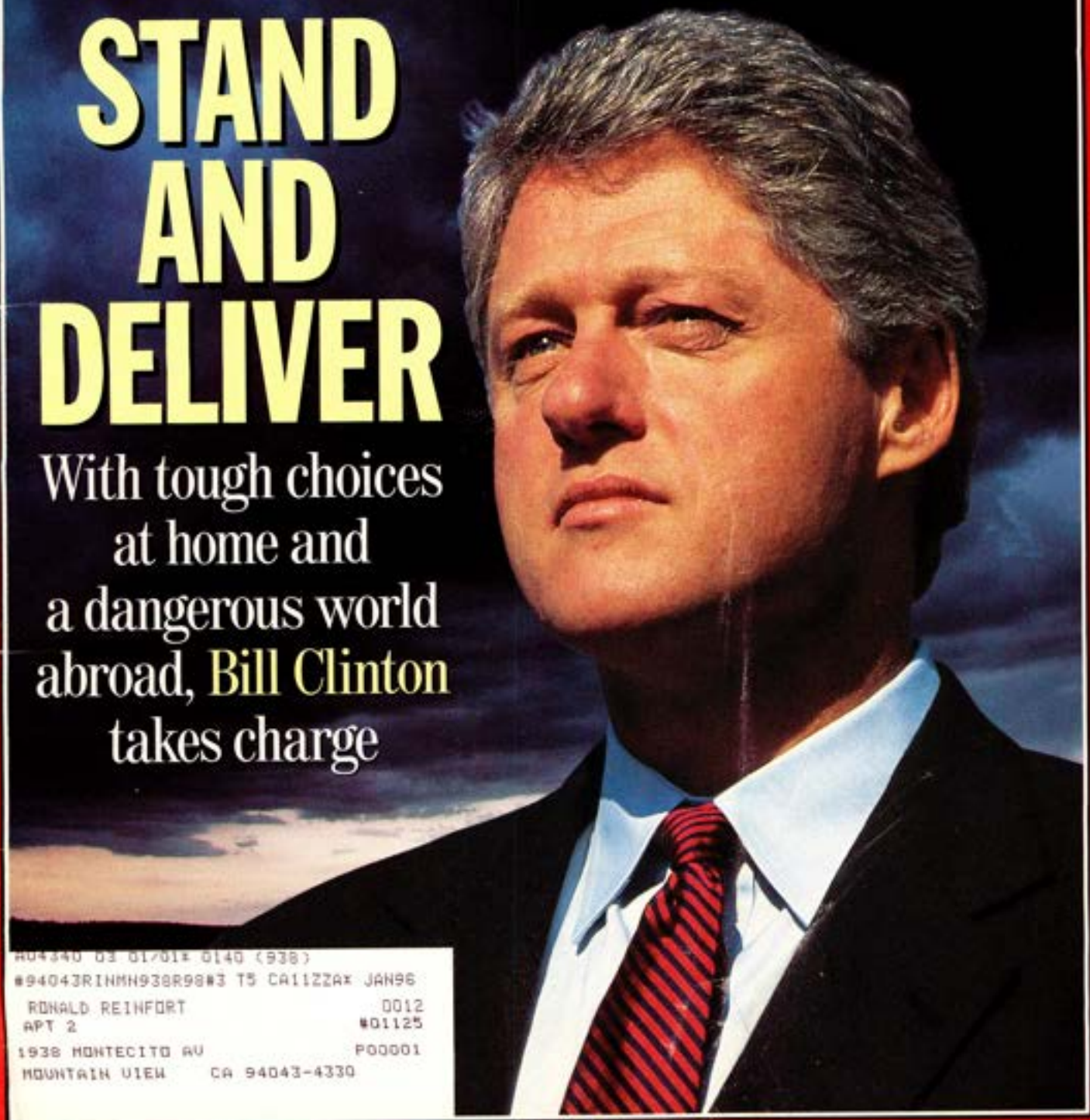
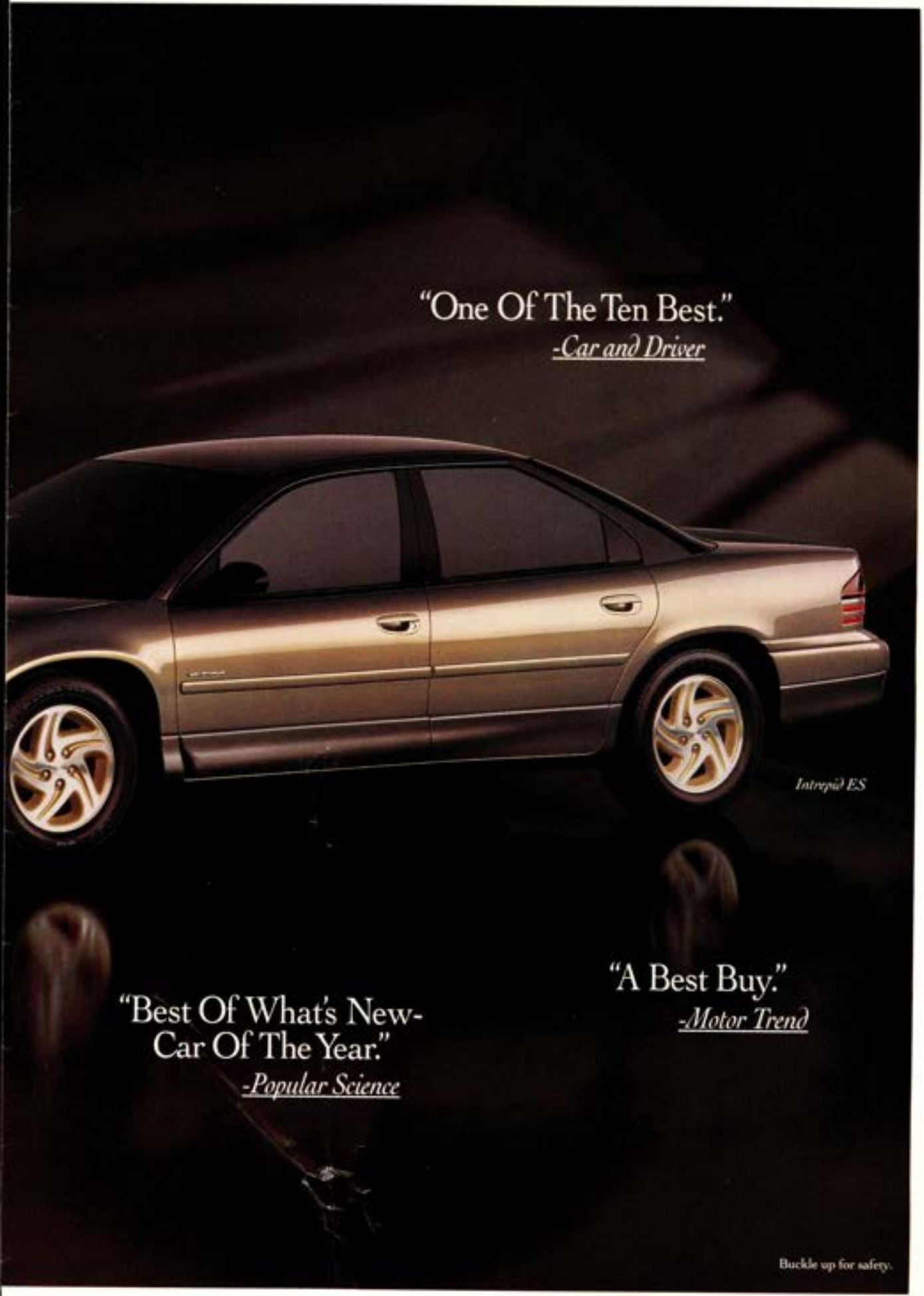
JANUARY 25, 1993 $2.95

# TIME

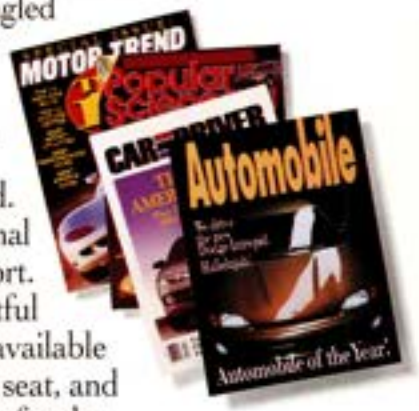


# STAND AND DELIVER

With tough choices at home and a dangerous world abroad, Bill Clinton takes charge


"One Of The Ten Best."
-Car and Driver
Intrepid ES
"A Best Buy."
-Motor Trend
"Best Of What's New-
Car Of The Year."
-Popular Science
Buckle up for safety.

We knew going in that the new Intrepid ES would be different. That it wouldn't look or act like the others in its class. And sure enough, the press has singled it out . . . for its dramatic cab-forward design. For the way it handles the road. For its exceptional room and comfort. And for thoughtful touches like its available integrated child seat, and standard airbags for the driver and front passenger.

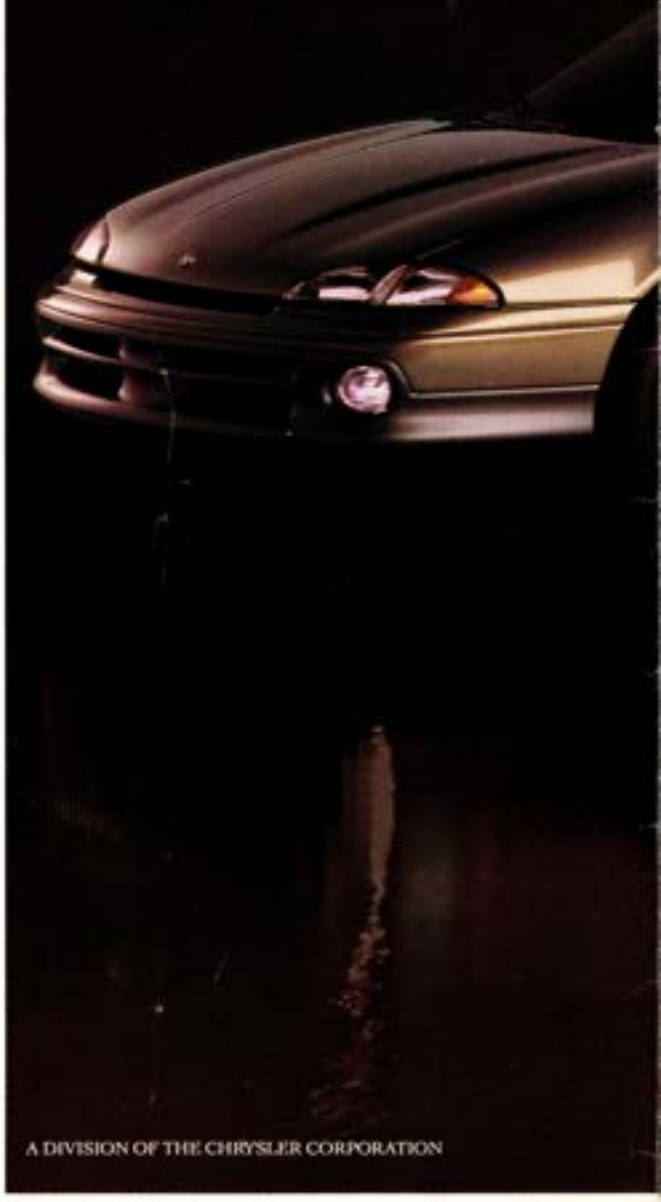



Intrepid has been called everything from innovative to revolutionary. And now that we've seen what's possible in a four-door sedan, we can't see building one any other way.

*Select Features*

- *Standard driver & front passenger airbags*
- *Available anti-lock brakes & traction control*
- *Available integrated child seat*
- *Standard rear seat heat & air ducts*
- *Available automatic temperature control system*
- *Standard four-wheel independent suspension*
- *Available 3.5 liter, 214 horsepower, 24-valve overhead cam V-6*
- *Choice of warranties: 7/70 powertrain or 3/36 bumper-to-bumper. See these limited warranties & restrictions at dealer. Excludes normal maintenance, adjustments & wear items.*
- *For still more information, call 1-800-4-A-DODGE*

"Automobile Of The Year."
*-Automobile Magazine*



INTREPID THE NEW DODGE

A DIVISION OF THE CHRYSLER CORPORATION

# DODGE INTREPID IS SO RADICALLY DIFFERENT, THE PRESS HAS STARTED CALLING IT NAMES.

# TIME

JANUARY 25, 1993 THE WEEKLY NEWSMAGAZINE VOLUME 141 NO. 4


## THE WEEK ..... 16


**NATION:** Promise? Not exactly

**WORLD:** One good man less

**BUSINESS:** "Operation Covent Garden" unravels in a London court

**SCIENCE:** The *Endeavour* crew tries out a $23 million gravity-sensitive commode



STEVE LISS/GAMMA-LIAISON FOR TIME

**After an awkward transition, finally a beginning**

## REVIEWS



### DEPARTMENTS



**Cover:** Photomontage. Clinton for TIME by Steve Liss; storm clouds by R. Hamilton Smith—ALLSTOCK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# FROM THE PUBLISHER

THE ADVENT OF A NEW ADMINISTRATION IS, QUITE NATURALLY, a time when many news organizations enact their own changing of the guard in the White House press room. TIME is among those inaugurating a new team, which will be in charge of chronicling the ups and downs of the incoming Clinton Administration. But we are doing so in a way that tries to combine a fresh perspective with historic continuity.

Moving to the White House beat will be Margaret Carlson, who has been deputy bureau chief for TIME in Washington. Carlson started her career at *Legal Times*, where she made use of her law degree from George Washington University, before moving on to *Esquire* and the *New Republic*. Since joining TIME in 1988, she has written in-depth profiles of personalities ranging from presidential candidates Bill Clinton, Jerry Brown and Pat Buchanan to actress Katharine Hepburn and comic Billy Crystal. "The challenge is to find the politics in Billy Crystal and the humor in Bill Clinton," she says. Her most recent subject was the relationship between Bill and Hillary Clinton, in an article that ran in the Man of the Year issue.

Carlson will join veteran White House correspondent Michael Duffy, who wrote this week's cover story on Clinton's Inauguration. Duffy covered the Pentagon and Congress before being assigned to the White House in 1988. A graduate of Oberlin College, he co-wrote the 1992 book *Marching in Place*, an analysis of the Bush Administration. (His co-author, Dan Goodgame, will be leaving the White House beat to become TIME's economic correspondent.) Duffy thinks Clinton will preside under more pressure than his predecessor. "Bush basically enjoyed a free ride for three years," he says. "But Clinton will have to live up to enormous expectations immediately."

Carlson and Duffy: New White House team

Both Carlson and Duffy think it will be important for Clinton to set the tone for his Administration during the first year. "He'll have to put on his stamp before the honeymoon ends and reality intrudes," says Carlson. In that regard, adds Duffy, "*it will be* interesting to see how Clinton balances the demands of his party's traditional constituencies with his pledge to be a new-style Democrat." TIME's new team will have to do some balancing of its own. No problem, says Duffy. "We're both very curious about what makes Clinton tick." The trick, says Carlson, "will be to share the agony and ecstasy in equal amounts." Like the new team that will occupy 1600 Pennsylvania Avenue, Carlson and Duffy are eager to get started.

Cynthia P. Vale


My family has been after me to quit smoking for a long time. So I've tried everything. Even cold turkey. But within a few weeks, I'd go right back to smoking again.

# NO ONE BELIEVED I WOULD EVER REALLY QUIT SMOKING.

Then my doctor suggested Habitrol™. Habitrol is a nicotine patch, indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. It's available only by prescription. When used as part of a comprehensive behavioral smoking cessation program, it's been clinically proven to increase the chances of quitting in the critical first three months. That's when nicotine withdrawal symptoms force many people back to smoking. Long term studies with Habitrol haven't been conducted.

As part of my smoking cessation program, I attended a support group my doctor recommended. He also gave me a free support kit with tips on getting through the rough times. And an audio tape for relaxation and motivation.

Because Habitrol contains nicotine, STOP smoking completely before starting your therapy with Habitrol and do NOT smoke or use any other nicotine containing products while you are receiving Habitrol therapy. If you're pregnant or nursing, or have heart disease, be sure to first find out from your doctor all the ways you can stop smoking. If you're taking prescription medicine or are under a doctor's care, talk with your doctor about the potential risks of Habitrol. Habitrol hasn't been studied in persons under 18, and it shouldn't be used for more than three months.

If you're really determined to quit, **ask your doctor** if Habitrol as part of a comprehensive smoking cessation program is right for you. **Or call 1-800-YES-U-CAN,** for a brochure today.

If you're tired of quitting and failing, Habitrol can help you with the nicotine craving and this can help you in your program to quit smoking. After that, it's up to you.

***IF YOU'VE GOT THE WILL, NOW YOU CAN HAVE THE POWER.***

**Habitrol™**
(nicotine transdermal system)

BASEL Pharmaceuticals
Division of CIBA-GEIGY Corporation
Summit, New Jersey 07901


273-30879

See next page for additional important information.

**Habitrol™**
**(nicotine transdermal system)**

**Systemic delivery of 21, 14, or 7 mg/day over 24 hours**

**BRIEF SUMMARY. FOR FULL PRESCRIBING INFORMATION SEE PACKAGE INSERT.**

**INDICATIONS AND USAGE**
Habitrol treatment is indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. Habitrol treatment should be used as a part of a comprehensive behavioral smoking cessation program.

The use of Habitrol systems for longer than 3 months has not been studied.

**CONTRAINDICATIONS**
Use of Habitrol systems is contraindicated in patients with hypersensitivity or allergy to nicotine or to any of the components of the therapeutic system.

**WARNINGS**
Nicotine from any source can be toxic and addictive. Smoking causes lung cancer, heart disease, emphysema, and may adversely affect the fetus and the pregnant woman. For any smoker, with or without concomitant disease or pregnancy, the risk of nicotine replacement in a smoking cessation program should be weighed against the hazard of continued smoking while using Habitrol systems, and the likelihood of achieving cessation of smoking without nicotine replacement.

**Pregnancy Warning**
Tobacco smoke, which has been shown to be harmful to the fetus, contains nicotine, hydrogen cyanide, and carbon monoxide. Nicotine has been shown in animal studies to cause fetal harm. It is therefore presumed that Habitrol treatment can cause fetal harm when administered to a pregnant woman. The effect of nicotine delivery by Habitrol systems has not been examined in pregnancy (see PRECAUTIONS, Other Effects). Therefore, pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches. If Habitrol therapy is used during pregnancy, or if the patient becomes pregnant while using Habitrol treatment, the patient should be apprised of the potential hazard to the fetus.

**Safety Note Concerning Children**
The amounts of nicotine that are tolerated by adult smokers can produce symptoms of poisoning and could prove fatal if Habitrol systems are applied, or ingested by children or pets. Used 21 mg/day systems contain about 60% (32 mg) of their initial drug content. Therefore, patients should be cautioned to keep both used and unused Habitrol systems out of the reach of children and pets.

**PRECAUTIONS**
**General**
The patient should be urged to stop smoking completely when initiating Habitrol therapy (see DOSAGE AND ADMINISTRATION). Patients should be informed that if they continue to smoke while using Habitrol systems, they may experience adverse effects due to peak nicotine levels higher than those experienced from smoking alone. If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, the Habitrol dose should be reduced or Habitrol treatment discontinued (see WARNINGS). Physicians should anticipate that concomitant medications may need dosage adjustment (see Drug Interactions).

The use of Habitrol systems beyond 3 months by patients who stop smoking should be discouraged because the chronic consumption of nicotine by any route can be harmful and addicting.

***Allergic Reactions:*** In a 6-week, open-label dermal irritation and sensitization study of Habitrol systems, 22 of 220 patients exhibited definite erythema at 24 hours after application. Upon rechallenge, 3 patients exhibited mild-to-moderate contact allergy. Patients with contact sensitization should be cautioned that a serious reaction could occur from exposure to other nicotine-containing products or smoking. In the efficacy trials, erythema following system removal was typically seen in about 17% of patients, some edema in 4%, and dropouts due to skin reactions occurred in 6% of patients.

Patients should be instructed to promptly discontinue the Habitrol treatment and contact their physicians if they experience severe or persistent local skin reactions at the site of application (e.g., severe erythema, pruritus or edema) or a generalized skin reaction (e.g., urticaria, hives, or generalized rash).

***Skin Disease:*** Habitrol systems are usually well tolerated by patients with normal skin, but may be irritating for patients with some skin disorders (atopic or eczematous dermatitis).

***Cardiovascular or Peripheral Vascular Diseases:*** The risks of nicotine replacement in patients with certain cardiovascular and peripheral vascular diseases should be weighed against the benefits of including nicotine replacement in a smoking cessation program for them. Specifically, patients with coronary heart disease (history of myocardial infarction and/or angina pectoris), serious cardiac arrhythmias, or vasospastic diseases (Buerger's disease, Prinzmetal's variant angina) should be carefully screened and evaluated before nicotine replacement is prescribed.

Tachycardia occurring in association with the use of Habitrol treatment was reported occasionally. If serious cardiovascular symptoms occur with Habitrol treatment, it should be discontinued.

Habitrol treatment should generally not be used in patients during the immediate post-myocardial infarction period, patients with serious arrhythmias, and patients with severe or worsening angina pectoris.

***Renal or Hepatic Insufficiency:*** The pharmacokinetics of nicotine have not been studied in the elderly or in patients with renal or hepatic impairment. However, given that nicotine is extensively metabolized and that its total system clearance is dependent on liver blood flow, some influence of hepatic impairment on drug kinetics (reduced clearance) should be anticipated. Only severe renal impairment would be expected to affect the clearance of nicotine or its metabolites from the circulation (See CLINICAL PHARMACOLOGY, Pharmacokinetics).

***Endocrine Diseases:*** Habitrol treatment should be used with caution in patients with hyperthyroidism, pheochromocytoma or insulin-dependent diabetes since nicotine causes the release of catecholamines by the adrenal medulla.

***Peptic Ulcer Disease:*** Nicotine delays healing in peptic ulcer disease; therefore, Habitrol treatment should be used with caution in patients with active peptic ulcers and only when the benefits of including nicotine replacement in a smoking cessation program outweigh the risks.

***Accelerated Hypertension:*** Nicotine constitutes a risk factor for development of malignant hypertension in patients with accelerated hypertension; therefore, Habitrol treatment should be used with caution in these patients and only when the benefits of including nicotine replacement in a smoking cessation program outweigh the risks.

**Information for Patients**
A patient instruction sheet is included in the package of Habitrol systems dispensed to the patient. It contains important information and instructions on how to use and dispose of Habitrol systems properly. Patients should be encouraged to ask questions of the physician and pharmacist.

Patients must be advised to keep both used and unused systems out of the reach of children and pets.

**Drug Interactions**
Smoking cessation, with or without nicotine replacement, may alter the pharmacokinetics of certain concomitant medications.

| **May Require a Decrease in Dose at Cessation of Smoking** | **Possible Mechanism** |
|---|---|
| Acetaminophen, caffeine, imipramine, oxazepam, pentazocine, propranolol, theophylline | Diminution of hepatic enzymes on smoking cessation |
| Insulin | Increase of subcutaneous insulin absorption with smoking cessation |
| Adrenergic antagonists (e.g., prazosin, labetalol) | Decrease in circulating catecholamines with smoking cessation |

| **May Require an Increase in Dose at Cessation of Smoking** | **Possible Mechanism** |
|---|---|
| Adrenergic agonists (e.g., isoproterenol, phenylephrine) | Decrease in circulating catecholamines with smoking cessation |

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
Nicotine itself does not appear to be a carcinogen in laboratory animals. However, nicotine and its metabolites increased the incidence of tumors in the cheek pouches of hamsters and forestomach of F344 rats, respectively, when given in combination with tumor-initiators. One study, which could not be replicated, suggested that cotinine, the primary metabolite of nicotine, may cause lymphoreticular sarcoma in the large intestine in rats.

Nicotine and cotinine were not mutagenic in the Ames *Salmonella* test. Nicotine induced repairable DNA damage in an *E. coli* test system. Nicotine was shown to be genotoxic in a test system using Chinese hamster ovary cells. In rats and rabbits, implantation can be delayed or inhibited by reduction in DNA synthesis that appears to be caused by nicotine. Studies have shown a decrease in litter size in rats treated with nicotine during gestation.

**Pregnancy Category D** (see WARNINGS)
The harmful effects of cigarette smoking on maternal and fetal health are clearly established. These include low birth weight, an increased risk of spontaneous abortion, and increased perinatal mortality. The specific effects of Habitrol treatment on fetal development are unknown. Therefore, pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches.

Spontaneous abortion during nicotine replacement therapy has been reported; as with smoking, nicotine as a contributing factor cannot be excluded.

Habitrol treatment should be used during pregnancy only if the likelihood of smoking cessation justifies the potential risk of use of nicotine replacement by the patient, who may continue to smoke.

**Teratogenicity**
***Animal Studies:*** Nicotine was shown to produce skeletal abnormalities in the offspring of mice when given doses toxic to the dams (25 mg/kg/day IP or SC).

***Human Studies:*** Nicotine teratogenicity has not been studied in humans except as a component of cigarette smoke (each cigarette smoked delivers about 1 mg of nicotine). It has not been possible to conclude whether cigarette smoking is teratogenic to humans.

**Other Effects**
***Animal Studies:*** A nicotine bolus (up to 2 mg/kg) to pregnant rhesus monkeys caused acidosis, hypercarbia, and hypotension (fetal and maternal concentrations were about 20 times those achieved after smoking 1 cigarette in 5 minutes). Fetal breathing movements were reduced in the fetal lamb after intravenous injection of 0.25 mg/kg nicotine to the ewe (equivalent to smoking 1 cigarette every 20 seconds for 5 minutes). Uterine blood flow was reduced about 30% after infusion of 0.1 mg/kg/min nicotine for 20 minutes to pregnant rhesus monkeys (equivalent to smoking about 6 cigarettes every minute for 20 minutes).

***Human Experience:*** Cigarette smoking during pregnancy is associated with an increased risk of spontaneous abortion, low-birth-weight infants and perinatal mortality. Nicotine and carbon monoxide are considered the most likely mediators of these outcomes. The effects of cigarette smoking on fetal cardiovascular parameters have been studied near term. Cigarettes increased fetal aortic blood flow and heart rate, and decreased uterine blood flow and fetal breathing movements. Habitrol treatment has not been studied in pregnant humans.

**Labor and Delivery**
Habitrol systems are not recommended to be left on during labor and delivery. The effects of nicotine on the mother or the fetus during labor are unknown.

**Nursing Mothers**
Caution should be exercised when Habitrol therapy is administered to nursing women. The safety of Habitrol treatment in nursing infants has not been examined. Nicotine passes freely into breast milk; the milk-to-plasma ratio averages 2.9. Nicotine is absorbed orally. An infant has the ability to clear nicotine by hepatic first-pass clearance; however, the efficiency of removal is probably lowest at birth. The nicotine concentrations in milk can be expected to be lower with Habitrol treatment when used as directed than with cigarette smoking, as maternal plasma nicotine concentrations are generally reduced with nicotine replacement. The risk of exposure of the infant to nicotine from Habitrol systems should be weighed against the risks associated with the infant's exposure to nicotine from continued smoking by the mother (passive smoke exposure and contamination of breast milk with other components of tobacco smoke) and from Habitrol systems alone or in combination with continued smoking.

**Pediatric Use**
Habitrol systems are not recommended for use in children because the safety and effectiveness of Habitrol treatment in children and adolescents who smoke have not been evaluated.

**Geriatric Use**
Forty-eight patients over the age of 60 participated in clinical trials of Habitrol therapy. Habitrol therapy appeared to be as effective in this age group as in younger smokers.

**ADVERSE REACTIONS**
Assessment of adverse events in the 792 patients who participated in controlled clinical trials is complicated by the occurrence of GI and CNS effects of nicotine withdrawal as well as nicotine excess. The actual incidences of both are confounded by concurrent smoking by many of the patients. In the trials, when reporting adverse events, the investigators did not attempt to identify the cause of the symptom.

**Topical Adverse Events**
The most common adverse event associated with topical nicotine is a short-lived erythema, pruritus, or burning at the application site, which was seen at least once in 35% of patients on Habitrol treatment in the clinical trials. Local erythema after system removal was noted at least once in 17% of patients and local edema in 4%. Erythema generally resolved within 24 hours. Cutaneous hypersensitivity (contact sensitization) occurred in 2% of patients on Habitrol treatment (see PRECAUTIONS, Allergic Reactions).

**Probably Causally Related**
The following adverse events were reported more frequently in Habitrol-treated patients than in placebo-treated patients or exhibited a dose response in clinical trials.
Digestive system - Diarrhea*, dyspepsia*
Mouth/Tooth disorders - Dry mouth
Musculoskeletal system - Arthralgia*, myalgia*
Nervous system - Abnormal dreams†, somnolence†
Frequencies for 21 mg/day system
*Reported in 3% to 9% of patients.
†Reported in 1% to 3% of patients.
Unmarked if reported in < 1% of patients.

**Causal Relationship Unknown**
Adverse events reported in Habitrol- and placebo-treated patients at about the same frequency in clinical trials are listed below. The clinical significance of the association between Habitrol treatment and these events is unknown, but they are reported as alerting information for the clinician.
Body as a whole - Allergy†, back pain†
Cardiovascular system - Hypertension†
Digestive system - Abdominal pain†, constipation†, nausea*, vomiting
Nervous system - Dizziness*, concentration impaired†, headache (5%), insomnia*
Respiratory system - Cough increased†, pharyngitis†, sinusitis†
Urogenital system - Dysmenorrhea*
Frequencies for 21 mg/day system
*Reported in 3% to 9% of patients.
†Reported in 1% to 3% of patients.
Unmarked if reported in < 1% of patients.

**DRUG ABUSE AND DEPENDENCE**
Habitrol systems are likely to have a low abuse potential based on differences between it and cigarettes in four characteristics commonly considered important in contributing to abuse: much slower absorption, much smaller fluctuations in blood levels, lower blood levels of nicotine, and less frequent use (i.e. once daily).

Dependence on nicotine polacrilex chewing gum (replacement therapy) has been reported. Such dependence might also occur from transference to Habitrol systems of tobacco-based nicotine dependence. The use of the system beyond 3 months has not been evaluated and should be discouraged.

To minimize the risk of dependence, patients should be encouraged to withdraw gradually from Habitrol treatment after 4 to 8 weeks of usage. Recommended dose reduction is to progressively decrease the dose every 2 to 4 weeks (see DOSAGE AND ADMINISTRATION).

**OVERDOSAGE**
The effects of applying several Habitrol systems simultaneously or of swallowing Habitrol systems are unknown (see WARNINGS, Safety Note Concerning Children).

The oral $LD_{50}$ for nicotine in rodents varies with species but is in excess of 24 mg/kg; death is due to respiratory paralysis. The oral minimum lethal dose of nicotine in dogs is greater than 5 mg/kg. The oral minimum acute lethal dose for nicotine in human adults is reported to be 40 to 60 mg (≈1 mg/kg).

Two or three Habitrol 30 cm² systems in capsules fed to dogs weighing 8-17 kg were emetic, but did not produce any other significant clinical signs. The administration of these patches corresponds to about 6-17 mg/kg of nicotine.

Signs and symptoms of an overdose of Habitrol systems would be expected to be the same as those of acute nicotine poisoning including: pallor, cold sweat, nausea, salivation, vomiting, abdominal pain, diarrhea, headache, dizziness, disturbed hearing and vision, tremor, mental confusion, and weakness. Prostration, hypotension, and respiratory failure may ensue with large overdoses. Lethal doses produce convulsions quickly and death follows as a result of peripheral or central respiratory paralysis or, less frequently, cardiac failure.

**Overdose From Topical Exposure**
The Habitrol system should be removed immediately if the patient shows signs of overdosage and the patient should seek immediate medical care. The skin surface may be flushed with water and dried. No soap should be used since it may increase nicotine absorption. Nicotine will continue to be delivered into the bloodstream for several hours (see CLINICAL PHARMACOLOGY, Pharmacokinetics) after removal of the system because of a depot of nicotine in the skin.

**Overdose From Ingestion**
Persons ingesting Habitrol systems should be referred to a health care facility for management. Due to the possibility of nicotine-induced seizures, activated charcoal should be administered. In unconscious patients with a secure airway, instill activated charcoal via nasogastric tube. A saline cathartic or sorbitol added to the first dose of activated charcoal may speed gastrointestinal passage of the system. Repeated doses of activated charcoal should be administered as long as the system remains in the gastrointestinal tract since it will continue to release nicotine for many hours.

**Management of Nicotine Poisoning**
Other supportive measures include diazepam or barbiturates for seizures, atropine for excessive bronchial secretions or diarrhea, respiratory support for respiratory failure, and vigorous fluid support for hypotension and cardiovascular collapse.

**Safety and Handling**
Habitrol systems can be a dermal irritant and can cause contact sensitization. Although exposure of health care workers to nicotine from Habitrol systems should be minimal, care should be taken to avoid unnecessary contact with active systems. If you do handle active systems, wash with water alone, since soap may increase nicotine absorption. Do not touch your eyes.

**Disposal**
When the used system is removed from the skin, it should be folded over and placed in the protective pouch which contained the new system. The used system should be immediately disposed of in such a way to prevent its access by children or pets. See patient information for further directions for handling and disposal.

**How to Store**
Do not store above 86°F (30°C) because Habitrol systems are sensitive to heat. A slight discoloration of the system is not significant.

Do not store unpouched. Once removed from the protective pouch, Habitrol systems should be applied promptly since nicotine is volatile and the system may lose strength.

**CAUTION:** Federal law prohibits dispensing without prescription.

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**BASEL**
**Pharmaceuticals**
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Summit, New Jersey 07901

# LETTERS

**MAN OF THE YEAR**

> If Clinton can run the U.S. as well as he ran his campaign, we'll be O.K.
>
> *Stan Candwell*
> *Hattiesburg, Miss.*


BILL CLINTON EXEMPLIFIES THE HOPES and confidence we have in the future of the post-cold war world [MAN OF THE YEAR, Jan. 4]. I wish Bill and Hillary Clinton great success in the challenge of helping renew the American Dream with economic recovery, restoration of American confidence and reinvigoration of U.S. leadership of the world. For all its frailties and overindulgences, the U.S. is the only superpower with a distinctive, noble idealism grounded on indomitable faith in freedom.

*Wilson Y. Lee Flors*
*Quezon City, the Philippines*

WHAT'S THE SURPRISE? CLINTON HAS BEEN TIME's Man of the Week for 52 issues straight in 1992.

*Chandler Rosenberger*
*Bratislava, Slovakia*

WHAT A CURIOUS CHOICE FOR MAN OF the Year. In a year marked by quiet economic recovery, as America continued its cautious and thoughtful acceptance of leadership in the new and dangerous world order, you anoint Clinton simply for being there. You would have shown more decorum by containing your glee at his election for at least a year and giving him a chance to do something.

*Thomas V. Moore*
*Atlanta*

CONGRATULATIONS ON YOUR SELECTION. In my opinion, Clinton was the first and only choice. I am delighted that you agreed with me.

*Penny A. Marshall*
*Desert Hot Springs, Calif.*

HOW CAN YOU SERIOUSLY PRESENT CLINton as Man of the Year when there are people elsewhere around the globe who have sacrificed their lives for others, fought against hate, war and discrimination, and who overcame diseases, human malignancies and tragedies?

*Elke Walter*
*Lampertheim, Germany*

WHEN I FIRST SAW YOUR COVER, I couldn't help noticing that Clinton appeared to have two horns coming out of the top of his head. Looking closer, I saw that they were only parts of the letter *M* from the word TIME. I hope this doesn't indicate that Clinton is going to have a devil of a time reducing unemployment, cutting the budget deficit and increasing U.S. productivity!

*A. Russell Friberg*
*Chattanooga, Tenn.*

SO YOU THINK THAT CLINTON IS MAN OF the Year? In your dreams, TIME. You can have this issue back.

*Patrick E. Mallen*
*Greenlawn, N.Y.*

THROUGHOUT THE YEAR CLINTON MAINtained his integrity despite numerous ugly, partisan attacks. He ran an energetic, intelligent and ethical campaign. He chose an outstanding running mate in Al Gore. He has given me and many Americans a sense of pride in our leader in the White House.

*Georgeanne E. Finley*
*San Diego*

SELDOM IN HISTORY HAS A U.S. STATESman had so many options and opportunities as Clinton does. The end of the cold war has the world in an extreme state of flux. The choices that will be

# THINK OF IT AS CAVIAR FOR THE POWER HUNGRY.

## FORD TAURUS SHO

**WITH AUTOMATIC TRANSMISSION.**

If you crave power with more than a hint of sophistication, may we suggest the 1993 Ford Taurus SHO?

With the new, uniquely engineered automatic transmission or the 5-speed manual, the Taurus SHO promises an unforgettable taste of the road.

Begin with the sequential fuel-injected 24-valve 220 horsepower V-6. This racing-type engine is ideally balanced by the 4-wheel

independent sport-tuned suspension, so you'll enjoy exceptional performance.

And since even the most adventurous palate has a conservative streak, the Taurus SHO has standard anti-lock brakes, a standard driver's air bag supplemental restraint system, and the option of a right-front passenger's side air bag. Air bags, in conjunction with properly worn safety belts, are one of the most effective restraint systems available. The Ford Taurus SHO. A perfect way to satisfy your appetite for power.

Buckle up—together we can save lives.

**HAVE YOU DRIVEN A FORD LATELY?**

Ford

made during the next four years will greatly affect world politics for the next 20. I can only hope for the sake of peace and stability that Clinton will rise to the occasion and prove himself more statesman than politician.

*Matthew Trent*
*Cincinnati, Ohio*

I'M AMAZED THERE WAS EVEN A DISCUSsion about Man of the Year. It had to be Clinton. In the space of less than a year, he went from being a virtual unknown to being elected President of the U.S. I voted for Bush for a lot of reasons, but you have to admire the tenacity of Clinton's campaign. To paraphrase Dan Quayle: If Clinton can run the U.S. as well as he ran his campaign, we'll be O.K. for the next few years.

*Stan Caldwell*
*Hattiesburg, Miss.*

## A Special Celebration

REGARDING THE STORY ABOUT MY friends Bill and Hillary Clinton, I must bring to your attention a misimpression that remarks attributed to me may have left with your readers [MAN OF THE YEAR, Jan. 4]. Your article described an incident in which I stopped by the Governor's mansion to drop off a note of congratulations and found the Clintons celebrating with champagne. I spoke of a quiet yet joyful observance by the Governor and his wife of a special accomplishment, the passage of the educational-reform legislation they had worked to achieve for more than a decade. I have never seen them drink an alcoholic beverage before or since. I spoke of this experience as an example of one of the many times I have seen Bill and Hillary's deep love and affection for one another. They were relaxed and permitted an old friend to share in this moment of celebration and accomplishment.

*Carolyn Y. Staley*
*Little Rock*

## Last Refuge for Scoundrels

PRESIDENT NIXON SAYS HE WAS NOT A crook; President Reagan can't remember his part in the Iran-*contra* scandal; President Bush says he was out of the loop. Thanks to the instrument of presidential pardon [THE WEEK, Jan. 4], we can never officially refute these somewhat bizarre claims of innocence. The pardon writs afford a compelling documentation of the sordidness of the Nixon-Ford-Reagan-Bush concept of integrity. I wonder if the Founding Fathers ever suspected that Section 2 of Article II of the Constitution would provide a last refuge for scoundrels.

*Donald J. Montgomery*
*Okemos, Mich.*

## Blue Jays First

AS AN AMERICAN LIVING IN CANADA, I found it insulting to see the Toronto Blue Jays' victory in the World Series relegated to the ninth position on your list of the most important sporting events of the past year [THE BEST OF 1992, Jan. 4]. More sensitivity is needed toward your readers in Canada. Giving the new world champions only three lines is the utmost humiliation for Canada's avid baseball fans.

*Richard A. Hamelin*
*Downsview, Ont.*

## Lessons About Euthanasia

AS A NURSE WHO HAS WORKED IN INtensive care, hemodialysis and oncology, I am outraged both personally and professionally by Dr. Jack Kevorkian and the new fascination with euthanasia [ETHICS, Dec. 28]. Have we forgotten the lessons of history? The legalization

of killing always leads to unintended victims and unintended consequences. With health-care rationing on the horizon, even more people will be coerced into making a death decision. We must stand up for the principle that killing is incompatible with caring.

*Nancy Guilfoy Valko*
*St. Louis, Mo.*

KEVORKIAN IS ONLY ASSISTING PEOPLE to make a choice for themselves. I am 67 and in excellent health. I still work and enjoy life, but if that changes, I sincerely hope there is someone who will have the compassion to do for me what I will do for my beloved dog: help me go with dignity and ease. It seems unreasonable to insist on prolonging a life when there is no possible chance of improvement.

*Mary S.T. Rogers*
*Chesapeake, Va.*

HAVING LIVED IN A WHEELCHAIR FOR 25 years, unable to feed myself, brush my teeth or go to the bathroom, I am following reports about Kevorkian with intense interest. Unfortunately, the public is no longer outraged by Kevorkian's dealings with terminally ill or disabled people. Society's sensibilities are becoming dulled. We are now accepting a dangerous premise: that life lived in pain or in a wheelchair is not worth living, that you are better dead than disabled. Why do we consider it ethical and appropriate to prevent able-bodied people from committing suicide but fail to go that extra mile for disabled people, who are pitied as defenseless or helpless? Instead of making it easier for people to die, let's make it easier for them to live.

*Joni Eareckson Tada*
*Agoura Hills, Calif.*

## A Year Too Soon?

**You can't say our choice of Bill Clinton as Man of the Year met with overwhelming approval from our readers. In fact, of the hundred or so who have written us about it so far, most disagreed with the selection. Many were George Bush supporters who felt he should have been named. Others believed Ross Perot's accomplishments during the year had earned him the honor. And quite a few readers agreed with John MacLeod of Wenham, Mass., who commented, "Clinton? Nice try, but not quite yet. You gave him the honor in advance."**

## Correction

IN OUR ITEM ON THE OUT-OF COURT SETtlement that will add 400 plants and animals to the Federal Government's endangered-species list [THE WEEK, Dec. 28], TIME failed to give credit to the Fund for Animals, the organization that played the leading role in bringing the lawsuit that secured protection for these imperiled species.

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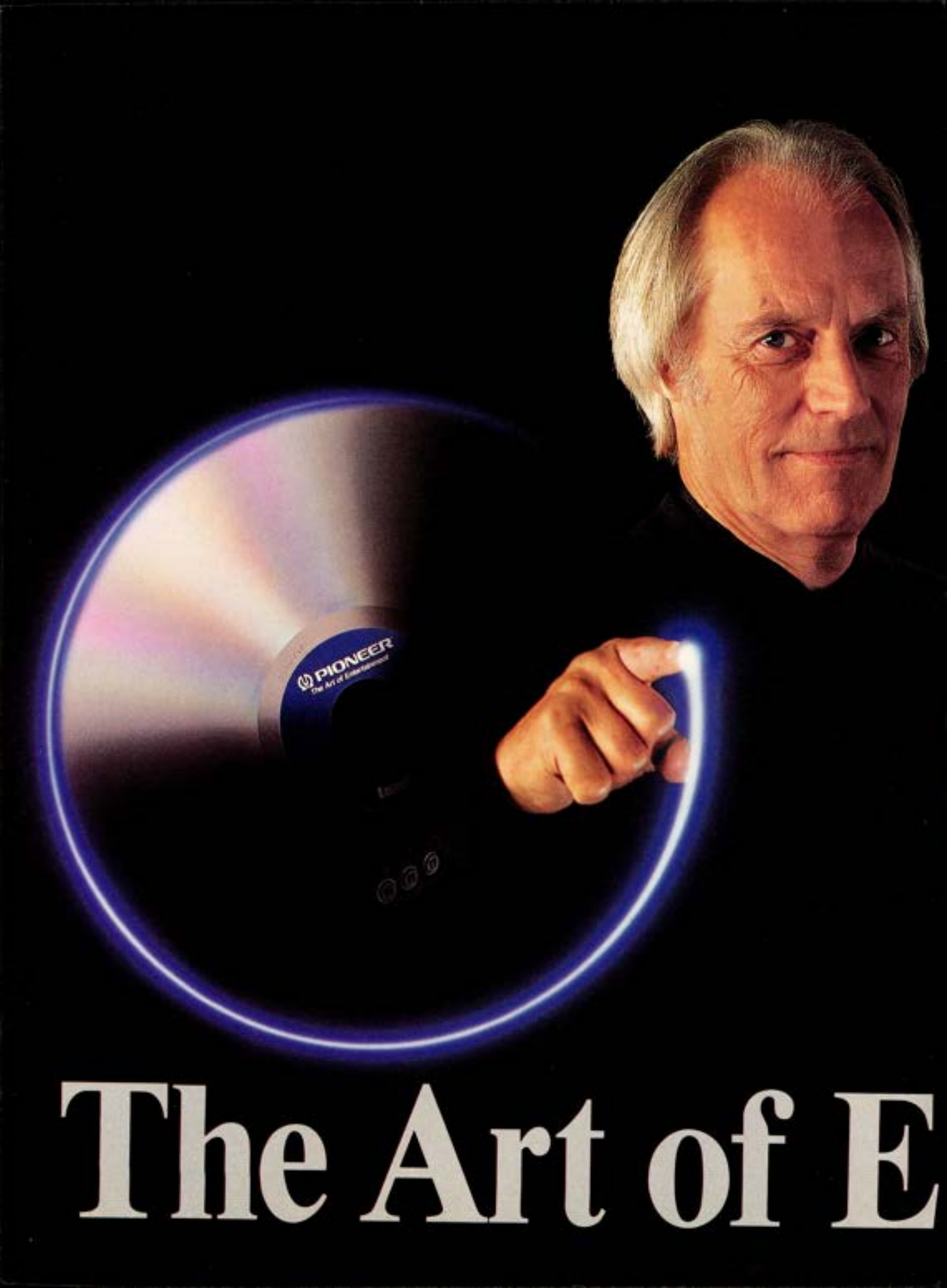


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—George Martin, Head of Air Studios Lyndhurst

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# ntertainment

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CODE: TIME/GENR/012593

NORPLANT® SYSTEM

levonorgestrel implants

# THE ANSWER TO MANY OF YOUR QUESTIONS ABOUT THE LATEST FORM OF BIRTH CONTROL.

### "IS THE NORPLANT SYSTEM EFFECTIVE?"

The NORPLANT® SYSTEM (levonorgestrel implants) provides 5 years of protection against pregnancy.* No reversible method of contraception is more effective than the NORPLANT SYSTEM. Of course, no method of birth control is 100% effective.

### "IS THE NORPLANT SYSTEM PROVEN?"

While it was introduced in the United States in 1991, it has been researched and tested for 20 years, in clinical trials and evaluations by over 55,000 women in 50 countries around the world.

### "IS THE NORPLANT SYSTEM CONVENIENT?"

Yes. Using a local anesthetic, your doctor places the NORPLANT SYSTEM under the skin of the inside of the upper arm in an office procedure that usually takes 10 to 15 minutes. There is nothing else required to prevent pregnancy. There is no daily remembering. There are no devices to use.

### "WHAT IF I WANT TO HAVE THE NORPLANT SYSTEM REMOVED BEFORE 5 YEARS ARE UP?"

The NORPLANT SYSTEM is a reversible method of contraception. You can choose to have the NORPLANT SYSTEM removed before the 5 years are up for any reason. Once removed, the contraceptive effect stops quickly, and you can become pregnant as rapidly as if you hadn't used the NORPLANT SYSTEM.

### "WHAT ABOUT SIDE EFFECTS?"

With the NORPLANT SYSTEM, there may be side effects. Menstrual cycle irregularity is the most common. Unexpected

bleeding or no bleeding at all may occur. Usually, however, those irregularities diminish after 9 to 12 months. Other possible side effects may include headache, nervousness, nausea and dizziness. Be sure to discuss side effects and individual concerns with your doctor since counseling is essential.

## "IS THE NORPLANT SYSTEM RIGHT FOR EVERY WOMAN?"

While the NORPLANT® SYSTEM (levonorgestrel implants) can be used with confidence by the majority of women, there are some women who should not use it for medical reasons. These include: women who are pregnant, have acute liver disease, unexplained vaginal bleeding, breast cancer, or blood clots in the legs, lungs or eyes. Your doctor can tell you more.

## "HOW DO WOMEN WHO HAVE USED THE NORPLANT SYSTEM FEEL ABOUT IT?"

The NORPLANT SYSTEM is well received and well liked by many American women. However, as with all products, some women discontinue use. In U.S. clinical trials of over 2400 women, approximately 20% of the women had the NORPLANT SYSTEM removed within the first year. The reasons were menstrual irregularities, other medical reasons, or personal reasons such as the desire to become pregnant. The results of a survey among 75 women who had used the NORPLANT SYSTEM for at least 1 year showed that of the 72% who responded, all stated they would recommend it to a friend.

## "HOW CAN I GET THE NORPLANT SYSTEM?"

The NORPLANT SYSTEM is only available through your doctor. Ask your doctor if the NORPLANT SYSTEM is right for you.*

**THE REVERSIBLE FIVE-YEAR CONTRACEPTIVE.**

**NORPLANT® SYSTEM**
*levonorgestrel implants*

*The NORPLANT SYSTEM does not prevent sexually transmitted diseases. For more information about this subject, speak with your doctor.

Please be sure to read the important information on the following page.

**BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR THE PATIENT**

**INTRODUCTION**

Each woman who considers using the NORPLANT® SYSTEM (levonorgestrel implants) should understand the benefits and risks of this form of family planning as compared with other contraceptive methods. The NORPLANT SYSTEM consists of six thin, flexible capsules, containing a synthetic hormone, levonorgestrel. They are inserted just under the skin on the inside of your upper arm during a minor, outpatient surgical procedure. This Summary is not a replacement for a careful discussion with your health-care provider.

**USE OF THE NORPLANT SYSTEM**

The NORPLANT SYSTEM is used to prevent pregnancy. It is a long-term (up to 5 years) reversible birth control method, which can be removed at any time. No contraceptive method is 100% effective. (See **"INSERTION/REMOVAL OF THE NORPLANT SYSTEM CAPSULES."**)

**WHO SHOULD NOT USE THE NORPLANT SYSTEM**

You should not have the NORPLANT SYSTEM inserted if you are pregnant or think you may be pregnant, or have:

- Acute liver disease; noncancerous or cancerous liver tumors;
- Unexplained vaginal bleeding (until a diagnosis is reached by your health-care provider);
- Breast cancer;
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes.

**OTHER CONSIDERATIONS BEFORE CHOOSING THE NORPLANT SYSTEM**

Tell your health-care provider if you or any family member has ever had:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram; diabetes; elevated cholesterol or triglycerides; high blood pressure; headaches; gallbladder, heart, or kidney disease; history of scanty or irregular menstrual periods.

Women with these conditions may need to be checked more often by their health-care provider if they choose the NORPLANT SYSTEM.

Be sure to inform your health-care provider if you smoke or are on any medications. The NORPLANT SYSTEM may be less effective in preventing pregnancy in heavier women. Discuss this with your health-care provider.

**RISKS OF USING THE NORPLANT SYSTEM**

**A. Risks based on experience with the NORPLANT SYSTEM**

1. *Irregular Menstrual Bleeding.* Most women using the NORPLANT SYSTEM experience some change in their usual monthly bleeding pattern. These menstrual irregularities vary from woman to woman. (See **"SIDE EFFECTS."**)

   It cannot be predicted what kind of change you may experience. If increased frequency of bleeding occurs, the quantity of blood lost is rarely enough to cause anemia, but there have been a few cases that required treatment. The irregularities frequently diminish gradually with continuing use.

   Because some NORPLANT SYSTEM users may not have regular bleeding, missed menstrual periods alone cannot be relied on to indicate pregnancy. Pregnancy tests should be done whenever a pregnancy may be possible. If, after a pattern of regular bleeding, you experience no bleeding for 6 weeks or more, pregnancy may be likely. If you are pregnant the capsules must be removed.
2. *Delayed Disintegration or Disappearance of Follicles.* Follicles in the ovary may become enlarged and cause discomfort. Most users would not be aware of them unless they were found on a routine physical exam. In most women, the follicles will disappear on their own and do not need surgery. Rarely, they may twist or rupture so that surgery is required. You should discuss this with your health-care provider.
3. *Ectopic Pregnancies.* Ectopic pregnancies (a pregnancy outside of the uterus) have occurred, although clinical studies have shown no increase in the rate of ectopic pregnancies per year among NORPLANT SYSTEM users as compared with users of no method or of IUDs. Symptoms include spotting and cramping pain, which usually begin shortly after the first missed period. Contact your health-care provider should you miss a period or experience abdominal pain.
4. *Blood Clotting Disorders.* Patients restricted to bed rest or who have limited movement for a prolonged period due to surgery or other illness may be at increased risk of developing blood clots. The NORPLANT SYSTEM may need to be removed in such patients.

**B. Risks based on experience with combination oral contraceptives**

Combination oral contraceptives ("the pill") contain a progestin such as levonorgestrel and an estrogen, another type of hormone. Some rare but serious side effects have been associated with the use of the pill. It is unknown whether the risks associated with use of the pill may also be risks with a progestin-only contraceptive like the NORPLANT SYSTEM.

The following pill associated risks should be discussed with your physician:

1. *Risk of developing blood clots* — Blood clots and blockage of blood vessels are the most serious side effects of taking the pill. In particular, a clot in the veins of the legs can cause inflammation and risk of further clots and a clot that travels to the lungs can cause a sudden blocking of the vessel carrying blood to the lungs, resulting in respiratory collapse and even death. Rarely, clots occur in the blood vessels of the eye and may cause double vision, impaired vision, or even blindness.
2. *Risk of heart attacks and strokes* — The pill may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain), angina pectoris, or heart attacks (blockage of blood vessels to the heart). Any of these conditions can cause death or serious disability.

   Use of the pill together with cigarette smoking greatly increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age who smoke. It is not known whether a similar interaction occurs with the NORPLANT SYSTEM. Therefore, women who use the NORPLANT SYSTEM should not smoke.
3. *High blood pressure* — Increased blood pressure has been reported among users of the pill. This risk has been shown to increase with long-term use.
4. *Gallbladder disease* — Users of the pill probably have a greater risk of gallbladder disease than nonusers. Since this risk may be related to pills containing high estrogens, it may not be a concern for NORPLANT SYSTEM users.
5. *Liver tumors* — In rare cases, the pill can cause noncancerous but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers. However, liver cancers are very rare.
6. *Cancer of the reproductive organs* — There is, at present, no confirmed evidence that the pill increases the risk of cancer of the reproductive organs in human studies. Recent studies have found no increased risk of developing breast cancer in the overall population of users. However, some of these same recent studies have found that certain subgroups of oral-contraceptive users may be at an increased risk, although no consistent pattern has been identified. Some studies have found an increase in the incidence of cancer of the cervix in women who use the pill. However, this finding may be related to factors other than the use of the pill.

**WARNING SIGNALS**

If any of these adverse effects occur following insertion of the NORPLANT SYSTEM call your health-care provider immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath;
- Pain in the calf;
- Crushing chest pain or heaviness in the chest;
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg;
- Sudden partial or complete loss of vision;
- Breast lumps;
- Severe pain or tenderness in the stomach area or lower abdominal area;
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood;
- Jaundice or a yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements;
- Heavy vaginal bleeding;
- Delayed menstrual cycles after a long interval of regular cycles;
- Arm pain;
- Pus or bleeding at implant site;
- Expulsion of a capsule.

**PRECAUTIONS**

**General**

1. *Physical Examination and Follow-Up* — Be sure to have periodic checkups as advised by your health-care provider while the capsules are in place.
2. *Carbohydrate Metabolism* — Blood sugar levels may be increased by progestin-only contraceptives such as the NORPLANT® SYSTEM (levonorgestrel implants). Diabetic and prediabetic patients should be observed carefully while using the NORPLANT SYSTEM.
3. *Liver Function* — The NORPLANT SYSTEM may need to be removed if yellowing of the skin or whites of the eyes occurs. Hormones may be poorly metabolized in patients with liver disease.
4. *Fluid Retention* — The pill may cause fluid retention with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or health-care provider.
5. *Emotional Disorders* — The NORPLANT SYSTEM may need to be removed if you become severely depressed.
6. *Contact Lenses* — If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or health-care provider.
7. *Insertion* — Prior to insertion of NORPLANT SYSTEM capsules, your health-care provider will inquire about your medical history and perform a physical exam. You should not have the capsules inserted if you are pregnant. NORPLANT SYSTEM capsules should be inserted within 7 days after onset of menstrual bleeding or immediately following an abortion to provide effective contraception during the first cycle of use. The capsules may be placed at other times during your menstrual cycle as long as you are not pregnant. However, then a nonhormonal contraceptive should also be used for the remainder of that cycle to prevent pregnancy.
8. *While Breast-feeding* — Women who are breast-feeding or intend to breast-feed should discuss this with their health-care provider when considering the use of the NORPLANT SYSTEM. Studies have shown no significant effects on the growth or health of infants whose mothers used the NORPLANT SYSTEM beginning six weeks after childbirth. There is no experience to support the use of the NORPLANT SYSTEM in breast-feeding mothers earlier than six weeks after childbirth.

**Drug interactions**

Certain drugs may interact with the hormone delivered by the NORPLANT SYSTEM to make the capsules less effective in preventing pregnancy. Such drugs include drugs used for epilepsy, such as phenytoin (Dilantin® is one brand) and carbamazepine (Tegretol® is one brand). You may need to use additional contraception when you take drugs that can make the NORPLANT SYSTEM less effective. Discuss this with your health-care provider.

**Drug/laboratory test interactions**

If you are scheduled for any laboratory tests tell your health-care provider that you are using the NORPLANT SYSTEM. Certain blood tests are affected by synthetic hormones.

**SIDE EFFECTS OF THE NORPLANT SYSTEM**

The most frequently reported side effects are menstrual cycle irregularities. Such changes vary from woman to woman and may include:

- Prolonged menstrual bleeding (more days than you would usually experience) commonly during the first months of use;
- Untimely bleeding or spotting between periods;
- Frequent onset of bleeding;
- Scanty bleeding;
- No bleeding at all for several months; or
- A combination of these patterns.

It cannot be predicted before insertion of the NORPLANT SYSTEM what kind of bleeding pattern you will have. Many women can expect an altered bleeding pattern to become more regular after 9 to 12 months. Despite the increased frequency of bleeding in some women, the monthly blood loss is usually less than normal menses. In fact, in some studies, patient blood counts have improved.

Contact your health-care provider if you experience heavy bleeding. If you have normal cyclic periods and then miss a period, a pregnancy test should be obtained. If you are pregnant, the NORPLANT SYSTEM must be removed.

In clinical studies, women using the NORPLANT SYSTEM have complained about the following conditions, which are probably related to the NORPLANT SYSTEM:

Headache; nervousness; nausea; dizziness; enlargement of the ovaries and/or fallopian tubes; inflammation of the skin, rash; acne; change of appetite; weight gain; breast tenderness; excessive growth of body or facial hair or hair loss; discoloration of the skin over the site of implantation (usually reversible); pain or itching near implant site; infection at implant site.

There are a number of other complaints reported by NORPLANT SYSTEM users or discovered by health-care providers which are thought to be possibly related to NORPLANT SYSTEM use:

Breast discharge; inflammation of the cervix, detected by physician; muscle and skeletal pain; abdominal discomfort; whitish discharge from the vagina and uterine cavity; vaginitis (inflammation of the vagina).

**INSERTION/REMOVAL OF THE NORPLANT SYSTEM CAPSULES**

NORPLANT SYSTEM capsules are inserted under the skin on the inner surface of your upper arm during a minor, outpatient surgical procedure under sterile conditions. A local anesthetic is used to numb a small area in the upper arm, after which a small incision, less than 1/8 inch long, is made in the same area. The insertion process takes about 10 to 15 minutes. The incision is covered with a small adhesive bandage and protective gauze.

The anesthetic usually prevents discomfort during insertion. When the anesthetic wears off, there may be some tenderness in the area for a day or two. Some bruising and swelling may also be present for a few days after the procedure. This should not interfere with your usual activities.

The capsules must be removed at the end of five years when the method starts to become less effective. You can choose to have them removed sooner, however, for any reason.

Just as for insertion, your health-care provider will apply a local anesthetic. Under sterile conditions, a small (1/8-inch) incision will be made through which all the capsules should be removed. The removal process usually takes from 15 to 20 minutes but may take longer. If some of the capsules are more difficult to remove, an additional visit and incision may be required.

Once the capsules are removed, the contraceptive effects cease quickly and a woman can become pregnant at a rate similar to women who have not used the method.

If you would like more information about the NORPLANT SYSTEM, a copy of the Prescribing Information can be obtained from your health-care provider.

This Brief Summary for Direct-to-Consumer Advertising is based on Current Norplant Patient Labeling PI 4069-1 Issued December 10, 1990 and Physician Labeling CI 4064-1 Issued December 10, 1990.




*Worldwide Leadership in Female Healthcare*

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